

suitable for sample preparation such as nucleic acid purification and reagents suitable for nucleic acid amplification and detection.

FIG. 5B shows a schematic rendering of disposable devices according to several embodiments of a third structure. The device comprises a containment vessel (501), such as a sealable polypropylene tube (501), a sample collection element (502) such as a hollow polyester stick, comprising a lumen (510) and a swab tip (503), a nucleic acid binding element (504) positioned within the containment vessel, a waste collection unit (507) coupled to the sample collection element, a plurality of reagent cartridges (515) coupled to the sample collection element and enveloping a plurality of reagents (530). The sample collection element is configured for removable coupling to the containment vessel. The plurality of reagent cartridges each comprises a capsule (516) and a plug (517). The plurality of reagents comprise reagents suitable for sample preparation such as nucleic acid purification and reagents suitable for nucleic acid amplification. The device further comprises an amplification detection unit (520) such as a Lateral Flow Dipstick (LFD).

FIG. 5C shows a schematic rendering of disposable devices according to several embodiments of a fourth structure. The device comprises a containment vessel (501), such as a sealable polypropylene tube (501), a sample collection element (502) such as a hollow polyester stick, comprising a lumen (510) and a swab tip (503), a nucleic acid binding element (504) positioned within the containment vessel, a waste collection unit (507) coupled to the sample collection element, a plurality of reagent cartridges (515) coupled to the sample collection element and enveloping a plurality of reagents (530). The sample collection element is configured for removable coupling to the containment vessel. The plurality of reagent cartridges each comprises a capsule (516) and a plug (517). The plurality of reagents comprise reagents suitable for sample preparation such as nucleic acid purification and reagents suitable for nucleic acid amplification. The device further comprises an amplification detection unit (520) such as a Lateral Flow Dipstick (LFD) and a disposable heater (506), such as a chemical heater, configured to heat the nucleic acid binding element.

FIG. 6A shows a schematic rendering of one of the plurality of reagent cartridges (515) coupled to the sample collection element (502) as shown in FIG. 5A-5B. The reagent cartridge comprises a capsule (516) and a plug (517), the capsule being connected to the lumen (510) of the sample collection element through an opening (518), the plug sealing the opening. The capsule envelopes one of the plurality of reagents (530). The reagent cartridge is configured to load the enveloped reagent through the lumen for placement in fluid communication with the nucleic acid binding element (504) upon removal of the plug from the opening.

FIG. 6B shows a schematic rendering of the waste collection unit (507) coupled to the sample collection element (502) as shown in FIG. 5A-5B. The waste collection unit comprises a chamber (601), the chamber comprising a first gap (603), and a plate (602), the plate coupled with the chamber and comprising a second gap (604). The chamber and the plate surround the lumen of the sample collection element, and at least one of the chamber and the plate is configured to be rotatable. When the first gap overlaps with the second gap, content of containment vessel (501) is adapted to flow into the waste collection unit.

According to the first aspect of the disclosure, apparatus for detecting a target nucleic acid in a sample is described. The apparatus comprises a containment vessel (301, 501), a sample collection element (302, 502) configured for remov-

able coupling to the containment vessel, a nucleic acid binding element (304, 504) positioned within the containment vessel. The sample collection element is configured to collect the sample and to transfer the sample to the nucleic acid binding element when the sample collection element is removably coupled to the containment vessel. The apparatus further comprises a plurality of reagents (330, 530) configured for placement in fluid communication with the nucleic acid binding element. The plurality of reagents comprises nucleic acid purification reagents and nucleic acid amplification reagents. The apparatus further comprises a heater (306, 506) configured to heat the nucleic acid amplification reagents in fluid communication with the nucleic acid binding element (see FIGS. 3A-3B).

The term “reagent” as used herein indicates a substance, a compound or a mixture that is added to a system in order to bring about a chemical reaction, to see if a reaction occurs or to purify an entity from a mixture. The term “nucleic acid purification reagent” as used herein indicates a reagent that is suitable for rinsing, washing, and/or purifying nucleic acid from a mixture of entities, including but not limited to a bodily sample, an environmental sample, blood, cells, bacteria, virus and fungi. Exemplary nucleic acid purification reagents include buffer, whatman purification reagent, TE buffer, saline, lavage, and the like. The term “nucleic acid amplification reagent” as used herein indicates a reagent that is suitable for amplifying one or more target nucleic acid. The term “amplifying” as used herein indicates any process or combination of process steps that increase the amount or number of copies of a molecule or class of molecules. Nucleic acid amplification may be carried out by any reaction or combination of reactions known in the art that are appropriate as recognized by those skilled in the art. For example, amplifying a target DNA molecule may be carried out by the polymerase chain reaction (PCR), amplifying a target RNA molecule may be carried out by a sequence of making cDNA copies of the target RNA, using PCR to increase the copy number of cDNA, and transcribing the cDNA copies to obtain RNA molecules having the same sequence as the target RNA molecule. Exemplary nucleic acid amplification reagents include polymerase such as BST polymerase, dNTPs, MgSO₄, betaine, suitable buffers. Selection of the reagents to be used in the methods or apparatus as herein described depends on various factors that are identifiable by those skilled in the art, including but not limited to the type and/or nature of the sample, types of impurity entities present in the sample, target molecule to be purified and/or amplified.

In some embodiments, the containment vessel (301, 501) is sealed when the sample collection element (302, 502) is removably coupled to the containment vessel.

In some embodiment, the apparatus further comprises a loading port (305), and the plurality of reagents (330) are configured for loading or extracting through the loading port for placement in or removal from fluid communication with the nucleic acid binding element (304).

In some embodiments, the sample collection element (302, 502) comprises a lumen (310, 510), and the sample collection element is configured to transfer the sample to the nucleic acid binding element (304, 504) via lavage delivered through the lumen when the sample collection element is removably coupled to the containment vessel (301, 501).

In some embodiments wherein the sample collection element (302, 502) comprises a lumen (310, 510), the plurality of reagents (330, 530) are configured for loading through the lumen for placement in fluid communication with the nucleic acid binding element (304, 504).